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Attorney Docket No.: UBC.P-020-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Gleave et al.

Serial No.:

10/080,794

Confirmation:

2924

Filed:

2/22/2002

Title:

TRPM-2 antisense therapy using an oligonucleotide having 2'O-(2-

methoxy)ethyl modifications

SUBMISSION OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicant requests that the references listed on Substitute Form PTO-1449, which is enclosed, be made of record in the Patent Office file relating to the above-captioned application. Copies of the references are being filed in the parent case, Serial No. 09/913,325.

No fee is believed to be due with this paper as we have not received an action on the merits. However, the Commissioner is authorized to charge any additional fees which might be due to Deposit Account No. 15-0610.

Respectfully submitted,

OPPEDAHL & LARSON LLP

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CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this paper and the attachments mentioned herein are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

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Substitute for form 1449A/PTO				Complete if Known			
				Application Number	10/080,794		
	INFORMATION DIS	CLO	SURE	Filing Date	2/22/2002		
	STATEMENT BY A	PPLI	CANT	First Named Inventor	Gleave et al.		
	(Use as many sheets as no			Art Unit	1635		
				Examiner Name	Karen Lacourciere		
Sheet	1	of	3	Attorney Docket Number	UBC.P-020-3		

	U.S. PATENT DOCUMENTS					
Examiner	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
Initials*			18.88 55 1111	Applicant of Orico Document	or Relevant Figures Appear	
		US-US 6,172,216 B1	1/9/2001	Bennett et al.		
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Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines.	Τ
No.¹	Country Code ³ -Number ⁴ - Kind Code ⁵ (<i>if known</i>)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages	τ ⁶
×	WO 02/22635 A1	3/21/2002	ISIS Pharmaceuticals, Inc.	Appear	Т
X	WO 03/062421 A1	7/31/2003	The University of British Columbia		
H	WO 03/072591 A1	9/4/2003	The University of British Columbia		
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	*	WO 02/22635 A1 WO 03/062421 A1	Country Code ³ -Number* - Kind Code ³ (<i>if known</i>) WO 02/22635 A1 3/21/2002 WO 03/062421 A1 7/31/2003	WO 02/22635 A1 3/21/2002 ISIS Pharmaceuticals, Inc. WO 03/062421 A1 7/31/2003 The University of British Columbia	Country Code* - Number* - Kind Code* (if known) Passages or Polovont Figures WO 02/22635 A1 3/21/2002 ISIS Pharmaceuticals, Inc. Appear WO 03/062421 A1 7/31/2003 The University of British Columbia

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INFORMATION DISCLOSURE

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Application Number

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First Named Inventor

Art Unit

(Use as many sheets as necessary)

Sheet

Complete if Known

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First Named Inventor Gleave et al.

Art Unit 1635

Examiner Name Karen Lacourciere

Attorney Docket Number UBC.P-020-3

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	TIVILE I magazino journal corial cympocium estalog etc.) date pege/e) velume jecue number/e) put		T²			
	×	GLEAVE ET AL., Use of Antisense Oligonucleotides Targeting the Antiapoptotic Gene, Clusterin/Testosterone-Repressed Prostate Message 2, To Enhance Androgen Sensitivity and Chemosensitivity in Prostate Cancer, Urology, 2001, Page(s) 39-49, Volume 58				
	X	GLEAVE ET AL., Antisense therapy: Current status in prostate cancer and other malignancies, Cancer and Metastasis Reviews, Page(s) 79-92, Volume 21				
	X	GLEAVE ET AL., Targeting anti-apoptotic genes upregulated by androgen withdrawal using antisense oligonucleotides to enhance androgen-and chemo-sensitivity in prostate cancer, Investigational New Drugs, 2002, Page(s) 145-158, Volume 20, Number 2, XP 009021411				
	*	GLEAVE ET AL., Antisense Targets to Enhance Hormone and Cytotoxic Therapies in Advanced Prostate Cancer, Current Drug Targets, Page(s) 209-221, Volume 4				
	X	JONES ET AL., Molecules in focus: Clusterin, The International Journal of Biochemistry & Cell Biology, 2002, Page(s) 427-431, Volume 34, XP002262319				
	*	MIYAKE ET AL., Antisense TRPM-2 Oligodeoxynucleotides Chemosensitize Human Androgen-independent PC-3 Prostate Cancer Cells Both <i>in Vitro</i> and <i>in Vivo</i> ¹ , Clinical Cancer Research, 5/1/2000, Page(s) 1655-1663, Volume 6				
	*	MIYAKE ET AL., Testosterone-repressed Prostate Message-2 Is an Antiapoptotic Gene Involved in Progression to Androgen Independence in Prostate Cancer ¹ , Cancer Research, 1/1/2000, Page(s) 170-176, Volume 60				
	K	MIYAKE ET AL., Synergistic Chemsensitization and Inhibition of Tumor Growth and Metastasis by the Antisense Oligodeoxynucleotide Targeting Clusterin Gene in a Human Bladder Cancer Model ¹ , Clinical Cancer Research, Page(s) 4245-4252, Volume 7				
	X	MIYAKE ET AL., Novel therapeutic strategy for advanced prostate cancer using antisense oligodeoxynucleotides targeting antiapoptotic genes upregulated after androgen withdrawal to delay androgen-indpendent progression and enhance chemosensitivity, International Journal of Urology, , Page(s) 337-349, Volume 8, Number 7,				
	×	ROSENBERG ET AL., Cluster: Physiologic and Pathophysiologic Considerations, International Journal of Biochemistry Cell Biology, Page(s) 633-645, Volume 27, Number 7				
	×	WILSON ET AL., Clusterin is a secreted mammalian chaperone, Trends in Biological Sciences, 3/1/2000, Page(s) 95-98, Volume 25, Number 3, XP004202536				

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Signature		Considered	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Examiner Initials* Cite No.¹ Include name of the author (in CAPITAL LETTERS), title of the article (when appropriat magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue nur and/or country where published.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²		
	X	WONG ET AL., Molecular characterization of human TRPM-2/clusterin, a gene associated with sperm maturation, apoptosis and neurodegeneration, European Journal of Biochemistry, Page(s) 917-925, Volume 227, Number 3, XP 001146404			
	X	ZANGEMEISTER-WITTKE ET AL., A Novel Bispecific Antisense Oligonucleotide Inhibiting Both bcl-2 and bcl-xL Expression Efficiently Induces Apoptosis in Tumor Cells ¹ , Clinical Cancer Research, 6/1/2000, Page(s) 2547-2555, Volume 6			
	*	ZELLWEGER ET AL., Antitumor Activity of Antisense Clusterin Oligonucleotides is Improved in Vitro and in Vivo by Incorporation of 2'-O-(2-Methoxy)Ethyl Chemistry, The Journal of Pharmacology and Experimental, 5/11/2001, Page(s) 934-940, Volume 298, Number 3			
	*	ZELLWEGER ET AL., Chemosensitization of Human Renal Cell Cancer Using Antisense Oligonucleotides Targeting the Antiapoptotic Gene Clusterin ¹ , Neoplasia, , Page(s) 360-367, Volume 3, Number 4			
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